Medicines Australia's Submission to the Privacy Act Review Report

5 April 2023

Medicines Australia welcomes the opportunity to contribute to the Attorney-General's Department's Privacy Act Review Report (**the Report**) Consultation.

Medicines Australia is the peak body representing the innovative, research-based, medicines industry in Australia. Our members discover, develop and manufacture medicines and vaccines that help people live longer, healthier lives and bring social and economic benefits to Australia.

As such, Medicines Australia is supportive of broadening the scope of research permitted without consent, broadening the research exemption. Strict safeguards already exist in the context of medical research and will continue to protect the personal information of research participants should these changes be implemented.

These changes to the Privacy Act will help facilitate new research and attract more global companies to invest in clinical trials in Australia. It is important Australia remains internationally competitive in attracting global companies to conduct trials here as they bring significant benefits to the economy and to Australian patients.

Clinical trials have contributed approximately $1.4 billion to the Australian economy through direct expenditure or investment in 2019, with additional flow-on effects of avoided healthcare costs, improving research infrastructure, and the creation of new jobs. The value derived from the clinical trials and research sector can also be seen in improved patient outcomes through access to innovative treatments and advancements to hospitals and medical expertise.[1]

Continuing to bring these benefits to Australia will, therefore, depend on maintaining or improving the existing system to ensure ongoing investment in clinical research remains efficient. Providing feedback on the Report is an important opportunity to ensure that any reforms the Australian Government implements are balanced, effective, and help to support the development and access of new medicines in Australia.

Please find below the responses and comments from Medicines Australia and its members on the proposed amendments in the Privacy Act Review Report.

[1] https://www.mtpconnect.org.au/images/MTPConnect_2021_AustraliasClinicalTrialsSectorReport.pdf

1. Research

A. Should the scope of research permitted without consent be broadened? If so, what should the scope be?

The broadening of the current scope of research permitted without consent can promote new research and clinical trials, and it can be done without jeopardising the privacy of participants. Medicines Australia and its members are supportive of *Proposal 14.1 Introduce a specific legislative provision that permits broad consent for the purposes of research* and includes future purposes that are not practicably identifiable at the time where consent is being obtained.

Currently, some Human Research Ethics Committees (HREC) allow for research permitted without consent for research considered Low/Negligible Risk (LNR)[2] such as retrospective file reviews for academic study and research. These studies should continue to be permitted as they provide a basis for quality improvement programs, insight into disease processes, and patient responses to current and emerging treatments[3].

Should the government decide to broaden existing obligations in the Privacy Act in other sectors and adopt recommendations proposed in the Report, the research exemption should also be broadened at the same time to ensure the right to use research information is not curtailed. This will also ensure that Australia's competitive clinical research industry is not unintentionally harmed by the changes. A selective approach may increase the burden on research organisations seeking to comply, without providing an appropriate safe harbour exemption.

Medicines Australia's members go to great lengths to ensure privacy and consent requirements are compliant with existing regulations. There is a need for certainty around the intended scope of the research exemption, and assurances that this exemption is not subject to change and uncertainty.

If the scope of research permitted without consent is broadened, safeguards already operate within the healthcare delivery and research sector to ensure the protection of personal data. These include:

- Professional standards from the Therapeutic Goods Administration (TGA) such as Good Clinical Practice (GCP) that govern the use and disclosure of personal data.
- Institutional Review Boards that review clinical research protocols.
- Removing, protecting, and coding direct patient identifier data before it is sent to the pharmaceutical or medical device company sponsoring the study to ensure that it cannot be used to re-identify patients.
- Stringent methodologies employed consistently by all HRECs.

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[2] https://rgs.health.wa.gov.au/Documents/WA%20Health%20Research%20Authorisation%20Monitoring%20Form%20Guidelines.pdf

[3] https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/ethics/low-risk-and-negligible-risk-research

Additionally, the National Statement on Ethical Conduct in Human Research (developed by National Health and Medical Research Council, the Australian Research Council and Universities Australia), provides principles which guide research designs and practices.

B. Which entity is the most appropriate body to develop guidelines to facilitate research without consent?

Clinical research is already highly regulated with many protections and safeguards in place. There are several entities that play key roles in ensuring the safety of clinical research and should be appropriately consulted in the development of guidelines to facilitate research without consent. These include:

i. The National Health and Medical Research Council (NHRMC) – the NHMRC, given its specialist technical knowledge and skills, and its existing role in regulating clinical research, remains the most appropriate entity to develop and administer the guidelines.

ii. Public and Private Human Research Ethics Committees (HREC) – HRECs who review research proposals involving human participants to ensure they are ethically acceptable, are also suitable to provide insight in

iii. Medicines Australia – as the peak body of innovative pharmaceutical companies who play a significant role in industry-sponsored research in Australia, should also have input into developing guidelines for research without consent.

C. General Comments on Research

- The amended definition of consent, requiring that it be *"voluntary, informed, current, specific and unambiguous"* may be sensible in isolation. However, this creates several problems in practice in the research context, specifically due to the long and ongoing nature of the need for consent and data. Moreover, as outlined in the Report, *"It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection",* making it difficult for consent to remain *current* and *specific*.

- Complicating the consent process by requiring institutions to recontact patients to seek their consent throughout research projects (if deemed necessary by HRECs), due to the changes in the definition of consent, would not increase participant privacy protections. As other respondents in the Report have raised, this would only add to consent fatigue and deter patients from participating in clinical trials and receiving potentially life-saving treatments. This is especially the case for groups that are already underrepresented in clinical trials such as older adults[4]. Continuously updating consent forms would also increase the administrative burden on research staff.

- The proposed restrictions on collection, use and disclosure of personal information to be 'fair and reasonable', combined with the expanded definition of consent, create significant ambiguity and uncertainty for companies operating in Australia. Companies have traditionally relied on consent to provide certainty for their operations. Whilst the pharmaceutical industry has in-principle support for the collection, use and disclosure of personal information to be

[4] https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21638

fair and reasonable, the current Australian Privacy Principles (APPs) are fit for purpose and the additional prescriptive factors that entities would need to assess are excessive and administratively unmanageable. This will in turn discourage the use of data acquired with consent for use beyond those identified at the time of collection, potentially stifling innovation.

- Medicines Australia, along with other life sciences peak bodies and the Research and Development Taskforce[5], have been advocating for the harmonisation and streamlining of clinical trials ethics review and governance requirements. The establishment of the National One Stop Shop and National Clinical Trials Front Door is an opportunity that could help streamline and secure the collection, use, and flow of consent and other sensitive data.[6]

2. Overseas Data Flow

A. General comments on harmonisation and alignment with global regimes

- Our members, many of whom are global companies, actively support international harmonisation of data management and privacy regulation where possible. However, there are concerns with the issue of facilitating cross-border data transfers. The proposed amendments need to meet the requirements of the General Data Protection Regulation[7] (GDPR), and greater consideration should be given to aligning with global regimes.

  In particular, the proposed use of Standard Contractual Clauses (SCC) for use when transferring personal information overseas should align with the GDPR clauses already in existence. As the Report respondents suggest, *"SCCs should be designed in a way that is interoperable with the clauses developed by other jurisdictions to avoid organisations being required to enter into multiple SCCs."*

- Relying on certification schemes to provide substantially similar protection to the APPs can be a costly, inefficient, and unnecessarily burdensome system. While this may be useful as a complementary step, it should not serve as the predominant focus of the amendments to the Privacy Act.

- Medicines Australia and our members also supports the alignment of the Privacy Act with the revised National Medicines Policy (NMP). One of the key enablers of the success of the NMP is ensuring the responsible collection, secure storage, appropriate use, management and sharing of data and information.[8]

[5] https://www.medicinesaustralia.com.au/policy/clinical-trials/research-development-task-force-rdtf/
[6] https://www.safetyandquality.gov.au/national-one-stop-shop-national-platform-health-related-human-research
[7] https://gdpr.eu/

[8] https://www.health.gov.au/sites/default/files/2022-12/national-medicines-policy.pdf

3. Personal information, de-identification and sensitive information

A. General comments on the proposed amendments to the definition of personal information

The proposed amendments to the definition of personal information, which changes information *"about"* an individual to information that *"relates to"* an individual, are unnecessary and make the definition of personal information too broad and uncertain. Information that "relates to" a person is a broad, potentially endless, set of information. The Report suggests the intent of the amendments to the definition of personal information is not to significantly change the scope but to clarify. However, these amendments only further add ambiguity.

B. General comments on de-identified information

Although Medicines Australia's members would mostly use coded data in industry-sponsored clinical trials and research, further clarity should be provided around those controls which might be applicable to "de-identified" information, particularly where the information includes genetic or genomic data.

Medicines Australia and its members look forward the outcomes of the recommendations following the Privacy Act Review Report, and that any reforms the Australian Government implements consider the feedback provided during this process.

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